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Supreme Court of the United States

TC HEARTLAND, LLC D/B/A HEARTLAND FOOD PRODUCTS GROUP,

Petitioner,

v.

KRAFT FOODS GROUP BRANDS LLC,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* GENENTECH, INC. IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*

Genentech, Inc., a member of the Roche Group, is a biotechnology company that employs approximately 11,000 people to fulfill its mission of discovering, developing, manufacturing, and commercializing medicines to treat patients with serious or life-threatening medical conditions. Founded in the 1970s as the first biotechnology company, Genentech has an extensive track record of bringing new disease treatments to patients, and continues an active program of filing and prosecuting patent applications to protect its inventions. Genentech is involved in all aspects of the patent system, including as a licensor of patent rights and as a licensee, and has participated in patent litigation in U.S. district courts across the country as both a plaintiff and as a defendant.

Among other types of biopharmaceutical patent litigation, Genentech has been and expects to continue to be involved in lawsuits under the Biologics Price Competition and Innovation Act (BPCIA) (relating to proposed biosimilar versions of biologics) and under the Hatch-Waxman Act (relating to proposed generic versions of small molecule drugs).

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[1] Pursuant to Supreme Court Rule 37.6, Genentech affirms that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented, either by express written consent (filed with this brief), or by filing a letter documenting consent.

Those cases raise issues distinct from those raised by Petitioner. Genentech submits this *amicus* brief to highlight venue issues unique to generic drug and biosimilar lawsuits, which are among the most statutorily structured types of patent litigation in the federal system. Genentech respectfully requests that the Court affirm the judgment of the Federal Circuit. Any reform of patent venue laws should be left to Congress, which can take into account the disparate venue issues raised by the broad variety of patent cases, including those under the Hatch-Waxman and BPCIA statutes.

SUMMARY OF ARGUMENT

The wide range of patent cases includes the non-practicing-entity cases that appear to animate the arguments of Petitioner and many of its supporting *amici*. It also includes, however, litigation between innovator companies like Genentech, on the one hand, who develop new drugs and shepherd those drugs through the lengthy FDA approval process, and generic drug and biosimilar manufacturers, on the other hand, who seek approval through the abbreviated pathways provided by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act of 2010 (the BPCIA).

Due in part to the statutory framework underlying biosimilar and generic drug litigation, these lawsuits raise unique venue issues. For example, the act of infringement in litigation concerning biosimilars and generic drugs is not the sale or use or marketing of the patented invention, but instead the act of submitting to the Food and Drug Administration (FDA) an abbreviated biologic license application (aBLA) or an abbreviated new drug application (ANDA). *See* 35 U.S.C. § 271(e)(2). Because the biosimilar or generic drug manufacturer controls when and whether to submit an application to FDA, and in that sense controls whether it will be sued, Hatch-Waxman and BPCIA suits do not present the types of issues discussed by many *amici curiae* regarding suits brought by, for example, non-practicing entities.

Moreover, because both the BPCIA and the Hatch-Waxman Act may substantially penalize a patent owner that does not timely file a valid suit against a biosimilar applicant or ANDA filer, innovator companies like Genentech are already statutorily incentivized to sue in a district in which the biosimilar applicant or ANDA filer has strong ties. Generic drug manufacturers and biosimilar applicants may assert that significant negative consequences flow from filing where venue is improper. The months needed to litigate venue can themselves effect harm to the innovator. This is one reason, for example, why so many Hatch-Waxman suits are brought in Delaware and New Jersey, home to many pharmaceutical companies, including those who produce generic drugs.[2]

The statutory mechanism for resolving patent disputes under the Hatch-Waxman Act has been a

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[2] *Amicus curiae* GPhA suggests this concentration of Hatch-Waxman cases bespeaks forum shopping. It does not. It reflects that the majority of the U.S. pharmaceutical industry—both innovative and generic—has a presence in Delaware, New Jersey, or Pennsylvania, with nineteen of the thirty-one listed 2016 GPhA Regular Members incorporated in Delaware or New Jersey. *See* Delaware Economic Development Office, *A Flourishing Life Sciences Industry*, http://dedo.delaware.gov/Industries/Life-Sciences (last visited Mar. 7, 2017); List of 2016 GPhA Regular Members, http://www.gphaonline.org/about/membership/ (last visited Mar. 7, 2017).

Despite this concentration, however, twenty-seven percent of Hatch-Waxman cases from 2009 to 2015 were filed in districts other than Delaware and New Jersey. *See* Brian C. Howard & Jason Maples, Lex Machina, Hatch-Waxman/ANDA Litigation Report 2015, at 3–4. (Apr. 2016).

success. As *amicus curiae* the Generic Pharmaceutical Association ("GPhA") notes, over 88 percent of the prescription drugs dispensed in the United States are generic drugs, up from only around 19 percent of prescriptions when the Act came into force. The system is working.

It is within Congress's authority to change that system if it so chooses, but until such time as it does, this Court should ensure that its ruling in this case does not imperil the complex process through which generic and biosimilar drugs reach the market.

ARGUMENT

I. AN OVERVIEW OF THE CURRENT SYSTEM

A. The Hatch-Waxman Act and ANDA Litigation

In the United States, approval for pharmaceuticals that are not biologics is based on the New Drug Application (NDA). *See Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). (Genentech addresses approval of biologics in Point I.B below.)

Because an innovator seeking approval of a new drug must typically conduct both animal testing and multiple phases of clinical trials in humans, all in accordance with FDA's rigorous standards for safety, the NDA process can be both lengthy and costly. Factoring in the additional costs of drug discovery prior to the start of the approval process, and the costs of failed drugs, the cost is even higher.

The Hatch-Waxman Act created a pathway for simplified approval of a generic version of an innovative drug that had itself already been approved through the NDA process. The proposed generic drug manufacturer may "file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd.*, 566 U.S. at 404–05. A generic drug manufacturer applicant need not submit preclinical animal data or data from clinical trials in humans. *See* FDA, The Generic Drug Approval Process, https://www.fda.gov/Drugs/NewsEvents/ucm508150.htm (last

visited Mar. 7, 2017). As its name suggests, the Drug Price Competition and Patent Term Restoration Act of 1984 had two goals: to allow lower-cost generic drugs to reach the market more quickly, and to restore to the innovator some of the patent life lost during the lengthy NDA process. *See* H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

As this Court has explained, "[b]ecause the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug." *Caraco Pharm. Labs., Ltd.*, 566 U.S. at 405. In order to ensure that any disputes regarding the scope or validity of the innovator's patents are timely resolved, the Hatch-Waxman Act established rules creating and governing so-called "ANDA litigations." Genentech addresses below how these ANDA-specific procedures interact with and are implicated by the venue statutes.

The Hatch-Waxman Act has been enormously effective in allowing generic drugs to reach the market. When it was adopted in 1984, generic drugs accounted for only 19 percent of prescriptions filled. *See* International Trade Administration, 2016 Top Markets Report: Pharmaceuticals at 4 (2016).[3] By 2000, that number reached 49%. *See* Pharmaceutical Research and Manufacturers of

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[3] *Available at* http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

America (PhRMA), 2016 Industry Profile (2016).[4] In 2015, generic drugs accounted for 88 percent of prescriptions filled but only 28 percent of drug costs. *See* International Trade Administration, 2016 Top Markets Report: Pharmaceuticals at 4 (2016); GPhA Report, Generic Drug Savings in the U.S. at 1 (2015).[5]

B. The BPCIA and Biosimilars Litigation

Congress enacted the BPCIA in 2010, as part of the Patient Protection and Affordable Care Act, with "certain similarities in its goals and procedures to the" Hatch-Waxman Act. *Amgen Inc.* v. *Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015).[6] Before the BPCIA, FDA could license a biologic medicine only under the traditional approval pathway of 42 U.S.C. § 262(a), which typically requires the full three phases of clinical trials. "An applicant filing a biologics license application ("BLA") typically provides clinical data to demonstrate the safety and efficacy of its product." *Amgen*, 794 F.3d at 1351.

The BPCIA established a new, abbreviated regulatory pathway, *see* 42 U.S.C. § 262(k), by which FDA could license a biologic product as "biosimilar" to or "interchangeable" with a biologic product that had itself previously been licensed under the traditional § 262(a) pathway. The BPCIA

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[4] *Available at* http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

[5] *Available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

[6] The *Amgen* decision is before this Court during this Term. *See* Nos. 15-1039 and 15-1195. The issues addressed in this brief are independent of the resolution of that case.

permits the biosimilar applicant to file an abbreviated BLA (an "aBLA") and to "reference" the innovator's license and thus rely on the innovator's own demonstration of safety and efficacy, saving the applicant time and expense. Congress established this pathway, again, to meet and to balance competing goals: "balancing innovation and consumer interests." BPCIA, Pub. L. No. 111–148, § 7001(b), 124 Stat. 119, 804 (2010).

To protect innovation, then, Congress also created a process by which the innovator—in the language of the BPCIA, the "sponsor"—receives information about the applicant's aBLA and proposed product, and receives notice and time to act on its patent rights, and to file suit to protect those rights. *See* 42 U.S.C. § 262(*l*). Genentech addresses below how these BPCIA-specific procedures interact with and are implicated by the venue statutes.

The BPCIA is, of course, far newer than the Hatch-Waxman Act. Thus far, however, FDA has licensed four biosimilar products: Zarxio® (filgrastim-sndz), which is Sandoz's biosimilar of Amgen's Neupogen® (filgrastim); Inflectra® (infliximab-dyyb), which is Pfizer Inc.'s biosimilar of Janssen Biotech, Inc.'s Remicade® (infliximab); Erelzi® (etanercept-szzs), which is Sandoz's biosimilar of Amgen's Enbrel® (etanercept); and Amjevita® (adalimumab-atto), which is Amgen's biosimilar of Abbott's Humira® (adalimumab).

II. ANDA AND BPCIA SUITS INVOLVE VENUE ISSUES NOT ADDRESSED BY PETITIONER

A. The Precipitating Act of Infringement Is Within the Defendant's Control

Much of the concern animating patent-venue debates stems from the possibility of a defendant being caught unaware that it is infringing a patent, and sued when it does not expect to be sued. Whether and to whatever extent that is a valid concern in other kinds of patent cases, Genentech notes here that it is not a concern in either ANDA or BPCIA cases. Instead, under both the Hatch-Waxman Act and the BPCIA, the trigger for pre-marketing litigation is entirely within the ANDA or aBLA filer's control. It is "an act of infringement to submit" an ANDA or aBLA, 35 U.S.C. § 271(e)(2)(A), (C), and whether and when to submit that filing is entirely up to the applicant.

ANDA and BPCIA suits are among the most structured and planned types of litigation in the federal system. Both the Hatch-Waxman Act and the BPCIA impose obligations on the innovator and the generic drug or biosimilar manufacturer that precede the filing of litigation. Non-compliance with those obligations risks the loss of important rights.

1. The Hatch-Waxman Act

In ANDA cases, the innovator must submit information to FDA concerning the patents it holds relating to its drugs to be published in the Approved Drug Products with Therapeutic Equivalence

Evaluations, commonly known as the Orange Book. *See Caraco Pharm. Labs., Ltd.*, 566 U.S. at 405–06. A company wishing to manufacture a generic drug may consult the Orange Book to determine when it will be able to file an ANDA and how long patent coverage is expected to last.

If, as is common, a generic drug manufacturer does not wish to wait for all of an innovator's patents to expire before introducing its product into the market, it may initiate a dispute with the innovator by submitting to FDA a "paragraph IV" certification stating that it contends that one or more of the Orange-Book listed patents are invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug. *See Caraco Pharm. Labs., Ltd.*, 566 U.S. at 407. The generic drug manufacturer must also provide a copy of that certification to the innovator/patent owner. *See* 21 U.S.C. § 355(j)(2)(B).

To avoid forfeiting certain rights, the innovator must then file suit within forty-five days of receiving notice from the generic drug manufacturer that it had filed an ANDA with FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

To facilitate such suits, Congress made the act of submitting an ANDA to FDA an act of patent infringement. Specifically, Congress provided that it "shall be an act of infringement" to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). This "artificial," or "technical," act of infringement is key to the Hatch-Waxman Act structure. *E.g.*, *Eli Lilly & Co.* v. *Medtronic, Inc.*,

496 U.S. 661, 678 (1990) ("artificial" act); *Acorda Therapeutics* v. *Mylan Pharms. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016) (same); *Ferring B.V.* v. *Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) ("technical" and "artificial" act).

Prior to FDA approval, and outside of the statutory safe harbor for acts "solely for uses reasonably related to" obtaining regulatory approval, *see* 35 U.S.C. § 271(e)(1), a generic drug manufacturer cannot lawfully make, use, sell, offer for sale, or import into the United States its product. That is, it cannot engage in "concrete, non-artificial acts of infringement." *Acorda*, 817 F.3d at 760. Therefore, prior to FDA approval of the ANDA and imminent market entry, the innovator may not be able to sue for traditional patent infringement under, for example, 35 U.S.C. § 271(a), (b), and (c). The technical act of infringement under Hatch-Waxman thus exists to facilitate resolution of patent disputes before FDA licensure. *See Acorda*, 817 F.3d at 760. But whether to submit an ANDA, and thus incur the risk of such litigation, is entirely within the control of the generic drug manufacturer.

2. The BPCIA

Here, the BPCIA closely parallels the Hatch-Waxman procedures. In the BPCIA, too, Congress made the filing of an aBLA a technical act of infringement permitting pre-licensure patent litigation. *See* 35 U.S.C. § 271(e)(2)(C); 42 U.S.C. § 262(*l*)(6). Which patents are infringed turns on whether the biosimilar applicant provides or "fails to provide" a copy of its aBLA and related manufacturing information "required under" 42

U.S.C. § 262(*l*)(2)(A). *Compare* 35 U.S.C. § 271(e)(2)(C)(i), *with* (ii).

B. The Hatch-Waxman Act and BPCIA May Impose Harsh Penalties on a Patentee Whose Suit Is Dismissed

The Hatch-Waxman Act and the BPCIA each specify consequences where the innovator does not timely file suit on the applicant's technical act of infringement. And generic drug manufacturers will assert—and, in the case of ANDA suits, have had some success in asserting—those consequences where the innovator files suit, but in an improper forum. As this Court considers the scope of patent venue, Genentech submits that it should consider potential unintended consequences of unduly restrictive venue laws.

1. The Hatch-Waxman Act

Under the Hatch-Waxman Act, as described above, once the innovator receives a generic drug manufacturer's Paragraph IV notice, it has forty-five days in which to sue. If the innovator does not sue within that time period, FDA may approve the generic manufacturer's ANDA despite the existence of potentially applicable patents. On the other hand, if the innovator timely sues, "FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier." *Eli Lilly & Co.* v. *Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009); *see also* 21 U.S.C. § 355(j)(5)(B)(iii). An innovator that does not sue

within the prescribed forty-five days could thus forfeit years of exclusivity.

Where innovators have sued within the forty-five days but the action is dismissed, a "failure to maintain" the suit "can result in the patent holder's loss of its patent claims." *Pfizer, Inc.* v. *Mylan, Inc.*, No. 1:09-CV-79, 2009 WL 10270101, at *1 (N.D.W. Va. Nov. 20, 2009). This led to a practice of innovators filing multiple suits in multiple jurisdictions—so-called "protective suits"—in order to "preserve [their] rights to the statutory 30-month stay of FDA approval." *AstraZeneca Pharms. LP* v. *Intellipharmaceutics Corp.*, No. 11-2973 (JAP), 2012 WL 525963, at *1 (D.N.J. Feb. 15, 2012); *see also, e.g.*, *Novartis AG* v. *Ezra Ventures, LLC*, No. 4:15-cv-00095 KGB, 2015 WL 4197692, at *2 (E.D. Ark. July 10, 2015); *Abbott Labs.* v. *Mylan Pharms., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) ("[P]atent holders are stuck between a jurisdictional rock and hard place: file suit in the forum of choice but risk losing patent protection if the suit is dismissed for personal jurisdiction, or file suit in the only known safe forum and incur all the inconvenience of litigating the matter in a distant location.").

In light of *Acorda*, and if this Court were to reverse the decision below, venue issues could become more important in ANDA cases. In *Acorda*, the Federal Circuit held that registering to do business in a state, authorizing an agent to accept service of process there, and filing an ANDA intending to direct sales of the approved generic drug into that state were sufficient to establish constitutional minimum contacts for specific

jurisdiction over the generic drug manufacturer in that state. *See* 817 F.3d at 763. *Acorda* may therefore reduce the likelihood of personal-jurisdiction battles in future ANDA cases.

Depending on the Court's resolution of this case and the role of 28 U.S.C. § 1391(c)(2) in patent cases, however, *Acorda* may have no effect on venue. The Federal Circuit specifically recognized that a finding of minimum contacts "does not end" any "venue inquiries." *Id.* The Federal Rules permit motions to dismiss for improper venue in lieu of an answer, *see* Fed. R. Civ. P. 12(b)(3), and Congress has authorized the federal courts, on a timely objection, to dismiss cases "laying venue in the wrong division or district" or to transfer them "if it be in the interest of justice." 28 U.S.C. § 1406(a), (b).

The Court should recognize that generic drug manufacturers will assert lack of venue to the extent possible in order to attempt to obtain dismissal of an innovator's lawsuit within the 45-day Hatch-Waxman period. While venue transfer may blunt the success of that strategy where district courts find that the interests of justice warrant transfer, the risk to innovators of venue fights are significant. And the likelihood that a venue controversy will be resolved within 45 days, absent (and perhaps even with) expedited motion practice, is vanishingly small.[7]

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[7] As Respondent and multiple *amici* point out, a holding that Section 1391(c)'s definitions of residence do not apply to Section 1400(b) also risks creating a venue framework under

2. The BPCIA

Here, the BPCIA differs significantly from the language of the Hatch-Waxman Act. As the Court will hear in the *Sandoz* v. *Amgen* case this Term, the BPCIA "Patents" provisions in subsection 262(*l*) include an "Immediate Patent Infringement Action" that the sponsor "shall bring" on certain listed patents within a 30-day period. *See* 42 U.S.C. § 262(*l*)(6)(a), (b). In enacting the BPCIA, Congress amended the provisions of Section 271 of Title 35 to prescribe consequences where the sponsor does not timely bring that § 262(*l*)(6) action or where it is dismissed, even without prejudice.

Specifically, instead of the remedies for the § 271(e)(2) technical act of infringement ordinarily provided by § 271(e)(4), the more limited remedy of § 271(e)(6)(B)—only a reasonable royalty—applies for any patent listed by the parties pursuant to 42 U.S.C. § 262(*l*)(4) or (5) for which an act of infringement:

> (I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of [42 U.S.C. § 262(*l*)(6)]; or
>
> (II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

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which there would be no proper venue in which to sue certain foreign corporations. Resp. Br. at 26.

35 U.S.C. § 271(e)(6)(A)(ii).

Thus far, these provisions have not been implicated in any of the lawsuits under the BPCIA, to Genentech's knowledge. Given the disputes that have already arisen, however, about many other aspects of the BPCIA, including but by no means limited to those in the *Sandoz* v. *Amgen* case, it is not hard to imagine a biosimilar applicant arguing that dismissal of an action for improper venue, even "without prejudice," or that filing a protective suit and not prosecuting it to judgment, implicates the penalties of § 271(e)(6). To be sure, the sponsor would have powerful counter-arguments about the purpose of these penalty provisions and their inapplicability to a dispute over venue. As this Court considers venue in patent cases, however, it should recognize that defendants will have a strong incentive to assert dismissal on any number of grounds, including for improper venue, because of the potentially harsh statutory consequences that could flow from such a dismissal in ANDA and BPCIA cases.

III. CONGRESS HAS RECOGNIZED THE SPECIAL STATUS OF ANDA AND BPCIA SUITS

When Congress enacted the 2011 Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, it indirectly addressed venue in patent cases by restricting joinder so that non-practicing entities could no longer sue unrelated defendants in a single action. *See* Br. of *Amicus Curiae* Unified Patents Inc. at 3. Thus, Congress created § 299 of Title 35, providing that "accused infringers may not be joined

in one action as defendants . . . based solely on allegations that they each have infringed the patent or patents in suit." 35 U.S.C. § 299(b). That provision is more strict than the joinder standard of Fed. R. Civ. P. 20, and can make it more costly and difficult for a non-practicing entity to pursue multiple defendants.

Notably, Congress created an express exemption that applies to ANDA and BPCIA cases. By its terms, § 299 does not apply to "an action or trial in which an act of infringement under section 271(e)(2) has been pled." 35 U.S.C. § 299(a). The technical acts of infringement for both ANDA and BPCIA cases are within § 271(e)(2). Thus, by statute, an innovator may join multiple generic drug manufacturers or multiple biosimilar applicants in the same case.

That makes sense. It is not uncommon for multiple generic drug manufacturers to target the same innovative drug.[8] Because, by law, the generic products must each be bioequivalent to the innovative product, and must each include the same instructions for use, *see* 21 C.F.R. § 314.94(a)(8)(iv), these suits will inevitably raise the same or very similar issues. Likewise, in the brief history of the BPCIA, there have already been lawsuits between

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[8] There have been ANDA suits involving up to twenty defendants. *See, e.g.*, *UCB, Inc.* v. *Accord Healthcare, Inc.*, No. 13-1206-LPS, 2016 WL 4376346 (D. Del. Aug. 12, 2016). Suits involving four or five defendants are not uncommon. *See, e.g.*, *In re OxyContin Antirust Litig.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014), *aff'd sub nom. Purdue Pharma LP* v. *Epic Pharma LLC*, 811 F.3d 1345 (Fed. Cir. 2016) (ANDA trial involving five defendants).

Amgen and each of Apotex and Sandoz about each of filgrastim and peg-filgrastim. Congress's decision to allow an innovator to sue multiple generic or biosimilar manufacturers in the same suit thus recognizes that there are significant benefits and efficiencies in having the issues raised by these cases decided by a single judge—benefits and efficiencies that likely could not be achieved through multidistrict litigation under 28 U.S.C. § 1407, as that statute provides for pretrial consolidation or coordination only.

As the Court considers the role of venue in patent cases, it should consider Congress's express invitation to join in one action multiple generic drug manufacturer and biosimilar applicants. As Respondent notes in its brief, Resp. Br. at 51–52, Petitioner's approach to venue may make it difficult to sue multiple defendants in the same forum. Should Petitioner's interpretation of 28 U.S.C. §§ 1391 and 1400(b) be adopted, the number of ANDA and BPCIA trials would likely multiply, with multiple district courts separately litigating the same or similar issues, placing a burden on the courts and the parties, frustrating the statutory purposes, and potentially delaying resolution of these litigations.

CONCLUSION

For the reasons set forth herein, Genentech respectfully requests that the Court affirm the judgment of the Federal Circuit. If patent venue reform is to occur, Congress should implement that reform.

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